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510(k) Summary

Applicant Name, Address, Telephone, Fax, E-Mail:

Helica Instruments Inc.
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Contact:

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1020 W. Bay Ave
Newport Beach, CA 92661-1015

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Submission Date:

-/-/03

Trade Name:

Helica Laparoscopic Cutting & Cauterising (LTC) Probe

Common Name:

Helium Cutting Probe

Classification:

Class II

Legally Marketed Predicate Device Name:

Helica "TC" Laparoscopic Cauterising (LT) Probe, K972267

Description of Device:

"The device is a helium gas electrosurgical coagulator for use in all soft tissue surgery-laparoscopic, endoscopic and open".

It consists of two parts:

- A power generator control unit with a Helium gas supply.
- An application probe.

An ionised gas plasma flame is generated in a controlled Helium gas flow at the end of a 4mm PTFE application tube (the probe). This produces a corona-type flame issuing from the open end of the probe with a high electron temperature but low molecular temperature of about 20C. When the probe is brought close (within 3 mm) to a surface connected to earth – such as human tissue – the corona-type flame changes to an arc discharge flame with a temperature of approx. 800C. The inert Helium gas flow in which the discharge takes place protects the area of discharge and minimises oxidation.

This plasma flame can be used to stop blood flow from damaged tissue by cauterisation.

The electrical generator provides an alternating current at a fixed frequency in the kilo hertz range with a power supply range of between 2 and 30W.

Referring to the application probe, which the model is the LT, the L is for Laparoscopic and the T is the length.

The new probe is the LTC. This is a cutting probe where the 4mm PTFE tube retracts, exposing the point which is approximately 8-10mm long. This probe works by using the Corona flame passing between the point and the tissue at the nearest point which could be on the side of the probe. The point area which is hot then cuts through the tissue and cauterises small blood vessels as it passes through.

Statement of Intended Use:

"The device is a helium gas electrosurgical cutting and coagulator for use in all soft tissue surgery-laparoscopic ,endoscopic and open ".

Description of Modification:

The basic design of the Helica probe remains the same. However the handle of the LTC probe has been modified to allow the PTFE sheath to be retracted; this exposes the brass insert, which can then be used as a cutting instrument.

Summary of Non Clinical Tests:

In vitro comparison of the Helica thermal coagulator (HTC) and the argon beam coagulator (ABC); Dr. John Webb, Ph.D:

The helium unit does have a much better control of the depth of necrosis than that of the ABC, but slightly less control over the width, perhaps due to the significantly greater power applied by the ABC to get the same effect. However, the judgement of effect of each of these units while in use during surgery is visual and it will be easy to judge the spread of the effect and not easy to judge the depth.

It can therefore be concluded that the use of the HTC should be easier than the AB, even given similar results, and the HTC should be considered "safer" with its much lower power at point of application.

Substantial Equivalence:

The has the following similarities to those which previously received 510(k) clearance:

- have the same indicated use,
- use the same operating principle,
- incorporate the same design,
- incorporate the same materials,
- have the same shelf life,
- and are packaged using the same materials and processes.

In summary, described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2004

Helica Instruments, Inc.
c/o John B. Webb. Ph.D.
1020 W. Bay Avenue
Newport Beach, California 92661-1015

Re: K032969
Trade/Device Name: Helica "TC" Laparoscopic Cutting and Cauterising (LTC) Probe
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 15, 2004
Received: January 21, 2004

Dear Dr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):K032969

Device Name: Helica "TC" Laparoscopic Cutting and Cauterising (LTC) Probe

Indications For Use:
"The device is a helium gas electrosurgical cutting and coagulator for use in all soft tissue surgery- laparoscopic, endoscopic and open."

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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